UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 1, 1990

Mr. Miguel Manzano
Abbott Puerto Rico Operations
P.O. Box 278
Barceloneta, P.R. 00617

Dear Mr. Manzano;

This letter is in response to your letter to Becky Cuthbertson and the conference call on February 27, regarding the 40 CFR Part 259 medical waste regulations. The questions you submitted in your letter of October 23, 1989, are somewhat site specific, and without visiting your facility the information provided in this letter may be somewhat generic in nature. Also enclosed you will find copies of the Part 259 regulations, brochures prepared for the regulated community and copies of Questions and Answer Documents which have been prepared in response to commonly asked questions.

Section 259.30(b)(iv) excludes regulated medical waste (RMW) residues produced during treatment and destruction processes from the tracking requirements once the waste has been both treated and destroyed. Generators of RMW which is treated and destroyed on-site must comply with the storage requirements found at Section 259.42 prior to treatment and destruction. In your letter you asked if autoclaving culture plates would be considered "treatment and destruction," thereby excluding tile autoclaved items from the tracking system. The definition of treated RMW and destroyed RMW can be found in Section 259.10(b). Treated RMW is defined as "RMW that has been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed." Destroyed RMW is "RMW which has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking so that it is no longer generally recognizable as medical waste."

There are several treatment technologies, including autoclaving, which are generally recognized as appropriate methods to achieve a reduction or eliminate the potential for causing disease. While the autoclaving is an adequate treatment method for medical waste, provided proper equipment maintenance and quality assurance measures are performed, this technique is not generally considered to be a destruction method for medical waste.

- It is clear that the autoclaving process may alter the appearance of certain plastic items which are susceptable to high temperatures; however, the total waste stream of RMW usually does not contain just heat susceptable items. This technology has not generally been recognized as a destruction method because the physical composition of most RMW components found in the wastestream are not significantly altered and remain recognizable as RMW. The applicability of autoclaving as a destruction method for a specific waste component would be a site specific determination and could not be done without a site visit by EPA or state officials.

As discussed during the conference call, the Abbott laboratories in Puerto Rico has several manufacturing areas (e.g., hospital, diagnostic, pharmaceutical and chemical manufacturing areas) in which products are made and quality assurance/quality control activities take place. The Part 259 regulations define RMW as "any solid waste listed in Class 1-7 of Section 259.30(a) which are generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human. beings or animals, in research pertaining thereto, or in the production or testing of biologicals." Consequently, several of the manufacturing areas within your facility may be generating RMW.

During the course of manufacturing, quality assurance/quality control (QA/QC) procedures are performed on test kits, pharmaceuticals, etc., which may contain "biologicals or body fluids." Since these products contain "biologicals" (i.e., preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosis, immunization or treating human beings or animals, or in research pertaining thereto) or "body fluids" (i.e., liquids emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions) the wastes generated during production or testing of these products (QA/QC or product control) would be considered RMW. As noted in your letter the empty vials which have never been used in production are not a regulated medical waste; however, if these vials were used in the production of your test kit the vials could be classified under Class 4 Sharps as found in Section 259.30 (a).

Test kits which are produced with human urine instead of human serum however, would not be regulated medical waste because urine is not included in the definition of "body fluids." Additionally, environmental specimens (i.e., swabs of table tops, walls, air, etc.) which are taken within the general production area would not be considered RMW because these wastes are not generated in the production or testing of biologicals.

The use of microorganisms (infectious agents) in the Quality Control (Product Control) procedures is common practice. If these microorganisms are obtained commercially, they are usually categorized in accordance with their use of associated biohazard level. The preamble to 40 CFR Part 259 provides an example of infectious agents as those agents which are listed in Classes 2-4 of the CDC's Classification of Etiological Agents on Basis of Hazard (July, 1974). However, the ability of an organism to cause disease or adverse health impacts (i.e., to be pathogenic) is dependent on many factors, the susceptibility of the host, the characteristics of the organism, the route of exposure, and the dose. As defined in Section 259.10 (b), infectious agents are any organisms (such as a virus or a

bacteria) which are capable of being communicated by invasion and multiplication of body tissues and capable of causing disease or adverse health impact in humans.

Organisms found in Class 2-4 of CDC's 1974 publication would be included. Additionally, there have been a substantial number of microorganisms identified since this publication. Consequently, infectious agents not included in the CDC list may be regulated. The classification of an organism as infectious or non-infectious is very difficult. Generally all cultures from a medical or pathological laboratory should be considered RMW because they are covered either as a Class 1 or Class 4 waste in Section 259.30(a). Therefore, virtually any culture or stock is subject to the requirements of Part 259.

In the quality control procedures Abbott utilizes bacteria which have been obtained from the American Type Culture Collection (ATCC) and the Food and Drug Administration (FDA). Those microorganisms obtained from ATCC are classified in accordance with CDC's recommended biosafety levels. Please contact ATCC and FDA directly for further information regarding specific microorganisms.

Thank you for you patience, if you have any other questions or require further assistance please contact Mary Greene 202-475-7736.

Sincerely,

Michael Petruska
Waste Characterization Branch

cc: George Meyers, EPA Region II
Florida Forestier, Environmental Quality Board

FaxBack # 11486